REMARKS

Claim 114 is cancelled. Therefore, claims 1, 97, 108-113 and 115-119 are pending. Claim 111 was amended to improve clarity; claim 115 was amended in response to the rejection under § 101; and claim 118 was amended to correct dependency. No new matter is added by these amendments or new claims. Reconsideration of the claims is requested in view of the amendments and following remarks.

I. New Matter Rejection Under the First Paragraph of § 112.

Claims 114 and 118-119 were rejected as containing subject matter not described in the specification on the basis that the phrase "fragments of 40 amino acids". Claim 114 is cancelled, and claim 115 amended as an independent claim reciting "a fragment of SEQ ID NO:12 comprising amino acids 688-727." This amendment is supported by the specification on page 72 of the antisera obtained with amino acids 688 to 727 of Stat3. Accordingly, this rejection may now be withdrawn.

II. Rejections Under 35 USC § 101.

Claims 1, 97, and 108-119 were rejected for lack of utility on the basis that the claims are not supported by either a specific asserted utility or a well-established utility. Applicants respectfully traverse this rejection.

Applicants submit that Stat3 meets the requirements of § 101 by having a well-established utility that is specific, substantial, and credible, evidenced as follows. Initially, it is pointed out that the rejected claims are drawn to Stat3 proteins and immunogenic fragments and fusion proteins thereof, encoded by DNA molecules claimed in issued US Patents 6,124,118 and 6,030,808. Applicants submit that the Examiner's position that Stat3 lacks utility is inconsistent with the self-evident utility found for the encoding DNAs.

Further, as described at page 71 of the specification, Stat3 was found to be activated as a DNA binding protein through phosphorylation on tyrosine in cells treated with EGF. Accordingly, the pharmacological activity taught in the specification would lead one of skill in the art to recognize the use of Stat3 in modulating the EGF pathway.

The importance of the EGF pathway is evidenced by publications available at the time

this invention was made. For example, Gutowski et al. (1991) Cancer Research 51:5471-5475 and Mendelsohn (1988) Trans. Am. Clin. Climatol. Assoc. 100:31-38, describe antibodies binding the EGF receptor in competition with EGF as effective tumor-suppressing agents capable of preventing EGF-induced activation of receptor tyrosine kinase; Maurizi et al. (1992) Int. J. Cancer 52:862-866 describe the correlation of increased EGF receptor levels with cancerous laryngeal tissue specimens; and Humphreys et al. (1988) Cancer Res. 48:2231-2238 found EGF receptor gene amplification in six of eight glioma biopsies examined. Accordingly, Applicants submit that when the teaching of the specification is combined with the knowledge in the art at the time the application was filed, the activation of Stat3 by EGF would be recognized as useful by one of skill in the art as providing a method for modulating the negative effect of EGF. This is clearly a specific and substantial utility.

In light of the above remarks, Applicants submit that the rejection under § 101 is inappropriate and respectfully request that this rejection be withdrawn.

III. Rejection Under the First Paragraph of 35 USC § 112.

A. Claims 1, 97 and 108-119 were rejected for lack of enablement on the basis that the claimed invention is not supported by either a specific or substantial utility. This rejection is respecfully traversed. The above remarks responsive to the rejection under § 101 are fully applicable to this rejection and are herein specifically incorporated by reference. The pharmacological activity of Stat3 activation as a DNA binding protein in cells treated with EGF disclosed in the specification combined with the art recognized connection between EGF activation of the EGF receptor and cancer clearly provides Stat3 with a specific utility (modulation of the EGF pathway) that would be widely recognized by one of skill in the art upon reading the instant disclosure.

Further, in regard to claims 111-113, drawn to an immunogenic fragment of SEQ ID NO:12, it is believed that the description on page 72 of the specification of the antisera obtained with amino acids 688 to 727 of Stat 3 clearly refutes the Examiner's stated position as to which regions of SEQ ID NO:12 would be immunogenic fragments. Accordingly, it is respectfully requested that this rejection be withdrawn.

B. Claims 111-119 were rejected for lack of written description. Applicants respectfully

traverse this rejection.

Claim 114 is cancelled. Claims 111-113 are drawn to an immunogenic fragment of Stat3. This provides both a functional requirement (immunogenicity) and a sequence requirement (fragment of SEQ ID NO:12), for example, the immunogenic fragment comprised of amino acids 688-727 described at pages 72-73 of the specification. Further, claim 115 is amended to more clearly claim the isolated fragment comprising amino acids 688 to 727 of SEQ ID NO:12. Applicants submit that claims 111-113 and 115-119 are sufficiently described in the specification to meet the written description requirement, and in light of these amendments and remarks, respectfully request that this rejection be withdrawn.

III. Rejection Under the Second Paragraph of 35 USC § 112.

Claims 1, 97, and 108-119 were rejected as indefinite on the basis that claim 111 is unclear as to whether the fragment has the sequence of SEQ ID NO:12 or is from SEQ ID NO:12. This rejection is respectfully traversed. However, in an effort to fully cooperate with the Examiner, claim 111 is amended to clarity that the claim is drawn to an immunogenic fragment of Stat3. In light of this amendment, it is believed that the rejection should be withdrawn.

Conclusion

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

In the event that there are any questions concerning this Amendment, or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,
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Marked Up Version Showing Changes Made

111. (Amended) An immunogenic fragment of an isolated receptor recognition factor (RRF), Stat 3[, having the amino acid sequence of] (SEQ ID NO:12).

115. (Amended) [The] An isolated fragment of [Claim 114 wherein the 40 amino acids of] SEQ ID NO:12 [are] comprising amino acids 688 to 727.

118. (Amended) A fusion protein comprising the isolated fragment of Claim [114] 115.